

### **Claim Rejections – 35 U.S.C. 102**

In the Official Action, the Examiner rejected Claims 1, 10-26, 30-31, 39-47, and 53-67 under 35 U.S.C. § 102(e) as being anticipated by Fraser, et al. (U.S. Patent No. 6,755,841) (hereinafter "Fraser"). Contrary to the rejection, previously presented independent claims 1, 19, 24, 30, 41, 46, 53, 58 and 63, as well as the claims that depend therefrom, are not anticipated by Fraser, as Fraser fails to disclose all features of the claimed invention.

#### **Claims 1 and 10-18 are not anticipated by Fraser.**

Specifically, with regard to Claim 1, Fraser fails to disclose an instrument for inserting into an intervertebral space an intervertebral implant comprising a pair of arms in which the arms are separable away from each other for removal of the arms from the intervertebral implant.

In contrast to the present invention, Fraser discusses an installation tool with optional rails that may be attached to opposing levers of the installation tool. The insertion tool may be utilized to slidably dispose an artificial disc into an intervertebral space. Fraser does not disclose a pair of arms that separate away from each other for the removal of the arms from an intervertebral implant. Referring to Fraser, Figures 1-6, each lever 12, 14 can include a rail (not shown) that may be formed in the inwardly facing surfaces 42, 44 of each lever that is effective to be slidably disposed within a corresponding groove or channel formed in the implant. Fraser, column 6, lines 18-22. As shown in Fraser, Figures 8C and 8D, the implant is then inserted by advancement of a pusher block 18 until the artificial disc 24 is properly installed between adjacent vertebral bodies. Fraser, column 12, lines 41-44. The levers of the installation tool are

then removed away from the artificial disc by retracting the entire insertion tool, without separating the levers further. Fraser, Figure 8D. Therefore, Fraser fails to disclose an instrument with a pair of arms that separate away from each other for removal of the arms from the implant. Consequently, Fraser fails to anticipate claim 1 and, accordingly, as claims 10-18 are dependent on claim 1, Fraser fails to anticipate claims 10-18 as well.

**Claims 19 and 20-23 are not anticipated by Fraser.**

With regard to claim 19, Fraser fails to disclose a spacer located between the arms that limits movement of the upper and lower arms towards each other and also fails to disclose an intervertebral implant comprised of upper and lower parts.

First, Fraser discloses an instrument having a rail and track on the top and bottom sides of a pusher block to limit movement of the levers. However, Fraser does not disclose a spacer that limits movement of a pair of arms. In particular, Fraser, Figures 6 and 7A, refers to a rail 95 and track 97 of top and bottom sides of a pusher block 18<sub>a</sub> that limit movement of the levers 12, 14 with respect to each other. Fraser, column 7, lines 59-61. In the Official Action, the Examiner referred to a spacer 10. However, contrary to the Examiner's assertion, in Fraser, 10 refers to the installation tool 10 itself and not a spacer. Nowhere does Fraser refer to a spacer. Thus, Fraser fails to describe a spacer for limiting movement of upper and lower arms towards each other.

Second, Fraser, Figures 1 and 8A-8D, simply discloses an artificial disc 24 that is only described as a single unit and is inserted by the use of a pusher block 18 that advances the artificial disc 24 into the intervertebral space. Fraser,

column 12, lines 35-44. Therefore, Fraser also fails to disclose an intervertebral implant with upper and lower parts.

Based on the foregoing, Fraser fails to anticipate claim 19 and, consequently, Fraser also fails to anticipate claims 20-23, as they are dependent upon claim 19.

**Claims 24 and 25-26 are not anticipated by Fraser.**

With regard to claim 24, Fraser does not describe a pair of arms connected together at a single pivot connection, such that the arms move relative to each other about said pivot connection in the manner of scissors, as claimed. Further, Fraser fails to disclose an intervertebral implant having upper and lower parts.

With regard to the recited pivot connection, Fraser clearly discloses an instrument that includes opposed levers with a fulcrum and pusher block disposed between said levers, not a pair of arms connected to each other at a single pivot point. Referring to Fraser, Figures 1-3B, installation tool 10 includes opposed levers 12, 14 with a fulcrum 16 and pusher block 18 disposed between the levers 12, 14. Fraser, column 5, lines 24-29.

Furthermore, in the Fraser insertion tool, the levers do not move relative to one another in a scissor-like manner. In the present invention, pressing together the proximal end of the arms of the insertion tool causes the distal ends of the arms to come together in a scissor-like manner. In Fraser, however, pressing together the proximal ends of the insertion tool causes separation of the distal ends of the tool and thus the levers of the tool do not move relative to each other in a scissor-like manner. Fraser, column 7, lines 25-30. Additionally, Fraser,

Figures 1 and 8A-8D, describes the separation of the blade tips 50A, 50B as being accomplished by the movement of the pusher block 18, and not due to a scissor-like action. Fraser, column 12, lines 22-49. Therefore, Fraser fails to describe a pair of arms connected together at a single pivot connection, such that the arms move relative to each other about said pivot connection in the manner of scissors, as claimed.

Moreover, as discussed in detail above in regards to claim 19, Fraser fails to describe an implant containing upper and lower parts.

Based on the foregoing, Fraser fails to anticipate claim 24, and, accordingly, also fails to anticipate claims 25-26, as they are dependent upon claim 24.

**Claims 30, 31, and 39-40 are not anticipated by Fraser.**

With regard to claim 30, Fraser fails to disclose a method of inserting into an intervertebral space an intervertebral implant that has upper and lower implant parts that are urged towards each other by the ends of the arms of the insertion instrument, as claimed. As discussed in detail above in regard to claim 19, Fraser fails to describe an implant containing upper and lower parts. Further, as Fraser fails to describe an implant containing upper and lower parts, Fraser also fails to describe upper and lower implant parts that are urged towards each other. Therefore, as Fraser fails to disclose an intervertebral disc that contains upper and lower parts urged toward each other by the arms of the insertion instrument, Fraser thus fails to disclose a method of inserting such an intervertebral implant.

Based on the foregoing, claim 30 is not anticipated by Fraser, and, consequently, claims 31 and 39-40 are also not anticipated by Fraser, as they are dependent upon claim 30.

**Claims 41 and 42-45 are not anticipated by Fraser.**

With regard to claim 41, Fraser fails to describe a method of inserting into an intervertebral space an intervertebral implant having upper and lower parts wherein a spacer is inserted into the space between the upper and lower parts to limit movement of the upper and lower parts towards each other in the vicinity of the spacer, as claimed. As discussed in regard to claim 19, Fraser fails to disclose an intervertebral implant having upper and lower parts and also fails to describe a spacer. Thus, Fraser fails to disclose a method of inserting such an intervertebral implant with the use of a spacer. Based on the foregoing, claim 41 is not anticipated by Fraser, and, consequently, claims 42-45, as they are dependent upon claim 41, are also not anticipated by Fraser.

**Claims 46 and 47 are not anticipated by Fraser.**

With regard to claim 46, Fraser fails to disclose a method of inserting an intervertebral implant having upper and lower parts, wherein a spacer is moved onto a portion of the lower part and the upper and lower parts are urged together to secure the implant, with the spacer limiting movement of the upper and lower parts together, as claimed. Again, as discussed above in regard to claim 19, Fraser fails to disclose an implant having upper and lower parts or a spacer. Also, as mentioned in the discussion in regard to claim 30, Fraser does not teach urging the two parts of the implant together. Therefore, Fraser does not teach a method of using an implant having upper and lower parts that are urged together

and the use of a spacer with such an implant. Claim 46 is thus not anticipated by Fraser and, accordingly, claim 47, as it is dependent upon claim 46, is not anticipated by Fraser as well.

**Claims 53 and 54-57 are not anticipated by Fraser.**

With regards to claim 53, Fraser does not describe an instrument for inserting an intervertebral implant of the type having upper and lower parts and does not describe a spacer located between the arms holding the upper and lower parts of the implant, as claimed. As discussed above in regard to claim 19, Fraser does not disclose an implant having upper and lower parts and does not disclose a spacer. Therefore, claim 53, and claims 54-57, as they are dependent upon claim 53, are not anticipated by Fraser.

**Claims 58 and 59-62 are not anticipated by Fraser.**

With regard to claim 58, Fraser again does not describe an instrument for inserting an intervertebral implant of the type having upper and lower parts and does not describe a spacer located between the arms which hold the upper and lower parts of the implant, as claimed. The discussion in regard to claim 19 shows that Fraser does not disclose an implant having upper and lower parts and does not disclose a spacer. Therefore, claim 58, and claims 59-62, as they are dependent upon claim 58, are not anticipated by Fraser.

**Claims 63 and 64-67 are not anticipated by Fraser.**

Finally, with regard to claim 63, Fraser does not describe a method for inserting an intervertebral implant having upper and lower parts, wherein a spacer is placed between the upper and lower arms of an insertion instrument. The discussion in regard to claim 19, above, reveals that Fraser does not

describe an implant with upper and lower parts or a spacer. Thus, Fraser fails to disclose a method of using such an implant and a spacer. Consequently, Fraser fails to anticipate claim 63, as well as claims 64-67, as they are dependent upon claim 63.

Based on the foregoing, Applicants respectfully request that the rejection of claims 1, 10-26, 30-31, 39-47 and 53-67, as being anticipated by Fraser, be withdrawn.

### **Claim Rejections – 35 U.S.C. 103**

Claims 24-26 and 48-52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fraser in view of Thalgott (U.S. Patent No. 6,558,424) (hereinafter “Thalgott”). Contrary to the rejection, Fraser, in view of Thalgott, fails to make obvious the subject matter of the aforementioned claims. Fraser and Thalgott are directed to entirely different insertion tools and each insertion tool is designed for the highly specialized purpose of manipulating a completely different type of implant. Thalgott is directed to a tool for the insertion of a modular fusion cage, which includes a ramp element which is first inserted between two vertebrae, followed by insertion of a ring unit. Thalgott, column 9, lines 1-3. Although, the Examiner asserts that Thalgott “evidences the use of a spacer 26 mounted between the upper and lower arms for engaging an implant 5”, Thalgott element 26 refers to the posterior surface of the ramp member. Thalgott, column 4, lines 50-53. Moreover, Thalgott does not have an element 5, let alone “an implant 5,” as alleged by the Examiner. Fraser, on the other hand, is directed to an installation tool that includes a pair of opposed

levers that facilitates the insertion of an artificial disc, disposed between the levers, into an intervertebral space. Fraser, column 12, lines 22-49.

There fails to be any apparent reason why one of ordinary skill in the art would have combined the insertion tool for an artificial disc of Fraser with the insertion tool for a modular fusion device of Thalgott. In order for two references to be combined in an obviousness type rejection under 35 U.S.C. § 103(a), there must be “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l Co. v. Teleflex*, 550 U.S. \_\_\_\_ (2007), Slip Opinion at page 14. Although, the Examiner alleges that “it would have been obvious to one skilled in the art at the time the invention was made to modify the device of Fraser, as taught by Thalgott, to facilitate insertion of an implant into an intervertebral space,” such a reason has no basis in the references, let alone in the art, in general.

Moreover, the Examiner’s statement is merely conclusionary and no facts have been alleged by the Examiner to support such an assertion. For example, nowhere in the cited prior art references is there a disclosure of a problem with how the insertion tool of Fraser facilitates the insertion of an implant into an intervertebral space. To the contrary, Fraser, Figures 1 and 8A-8D, illustrate an insertion tool having two opposed levers 12, 14, which may include a rail (not shown) that facilitates the insertion of an artificial disc into an intervertebral space, wherein the rails may be slidably disposed within a corresponding groove or channel in the artificial disc. Accordingly, Fraser fails to recognize an advantage of the present insertion instrument, which includes a tool for the



insertion of an intervertebral implant having upper and lower parts that engage each other, as well an insertion tool for engaging such upper and lower parts of such an implant.

Even if, *arguendo*, one of ordinary skill in the art would combine Fraser with Thalgott, the combined disclosure fails to enable one of ordinary skill in the art to practice the invention, as claimed. Specifically, the Fraser insertion tool is a pair of levers that is designed to hold an implant comprised of a single unit by insertion of a rail within a corresponding groove or channel in the implant. Fraser, column 6, lines 18-22. The Thalgott insertion tool, to the contrary, is specifically designed to insert a ring member around a ramp member through the use of vise-grips attached to two opposing handles that move relative to each other in a scissor-like fashion. Thalgott, column 9, lines 1-6. The combined references fail to teach or in any way make obvious how one of ordinary skill in the art would accommodate the scissor-like handles of Thalgott and utilize them with the levers of the insertion tool of Fraser to facilitate insertion of an implant having upper and lower parts. Only using impermissible hindsight, using the present disclosure as a blueprint, would one of ordinary skill in the art know how to fashion an instrument to enable one of ordinary skill in the art to practice the invention, as claimed.

Furthermore, one of ordinary skill in the art would find no benefit to including the scissor-like vise-grips of Thalgott with the insertion tool of Fraser, as such scissor-like vise-grips would serve no purpose in the insertion of the implant, according to Fraser. In fact, modifying the insertion tool of Fraser to

move in a scissor-like fashion would hinder the disclosed function of the Fraser tool. The insertion tool in Fraser utilizes a pair of levers to separate adjacent vertebral bodies and then the implant is inserted by pushing the implant along rails. To accommodate separating adjacent vertebral bodies, Fraser teaches an instrument in which pressing the proximate end of the arms together causes the distal ends of the instrument to separate, thereby prying the adjacent vertebrae apart. If the Fraser instrument were to operate like the Thalgott scissor-like vise-grips, pressing the proximate arms together would close the distal end of the instrument, thus thwarting the mechanical advantage in the form of leverage achieved by being able to squeeze the arms together to pry apart adjacent vertebrae. The combined teachings of Fraser and Thalgott fail to in any way teach how the vise-grips of Thalgott, which move in a scissor-like fashion, would be used with the insertion tool of Fraser in order to apply a sufficient force to separate adjacent vertebrae and to insert an implant therebetween. Therefore, there fails to be any benefit derived from combining the insertion tools of Fraser and Thalgott.

Turning now specifically to the claims rejected, with regard to claim 24, the prior art, individually or in combination with one another, fails to teach or in any way make obvious an instrument for inserting an intervertebral implant having an upper or lower part, each connected to a pair of arms that are pivotally connected to each other through a single pivot connection. The prior art, individually, or in combination with one another, fails to teach or in any way make obvious an intervertebral implant having an upper and lower part, much less an insertion tool

comprised of a pair of arms connected together at a single pivot connection for the insertion of such an implant. Therefore, claim 24 is not taught or made obvious by the prior art, either alone or in combination. Moreover, as claims 25 and 26 are dependent on claim 24, the prior art, individually or in combination with one another, also fails to teach or in any way make obvious the instrument described in claims 25 and 26.

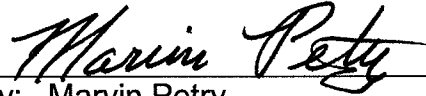
With regard to claim 48, the prior art, individually or in combination with one another, fails to teach or in any way make obvious a method for inserting an intervertebral implant having upper and lower parts through the use of an insertion instrument whose arms move in a scissor-like manner about a single axis pivot. As mentioned above, the prior art, individually or in combination with one another, fails to teach or in any way make obvious an instrument for inserting an intervertebral implant having an upper or lower part, each connected to a pair of arms that are pivotally connected to each other through a single pivot connection. Thus, the prior art, individually or in combination with one another, fails to teach or in any way make obvious a method of inserting such an implant through the use of such an insertion tool. Therefore, claim 48 is not taught or made obvious by the prior art, either alone or in combination. Additionally, as claims 49-52 are dependent on claim 48, the prior art, individually or in combination with one another, also fails to teach or in any way make obvious the method of claims 49-52.

Based on the foregoing, Applicants respectfully request that the rejection of claims 24-26 and 48-52 under 35 U.S.C. § 103(a) as being unpatentable over Fraser, in view of Thalgott, be withdrawn.

In view of the remarks provided, it is submitted that the present application is in condition for allowance.

Respectfully submitted,

Date: November 20, 2007

  
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